

Form PTO-1449  
(REV. 8-83)

U.S. Department of Commerce  
Patent and Trademark Office

Atty. Docket:  
2003080-0054  
(SK-893-US)

In re Application No.  
09/641,742

**SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT**

(Use several sheets if necessary)

Applicant: Danishefsky *et al.*

Filing Date:  
August 18, 2000

Group:  
1642

**U. S. PATENT DOCUMENTS**

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
KAC	5,683,674	Taylor-Papadimitriou <i>et al.</i>	Nov. 4, 1997	424	1.49
KAC	6,222,020	Taylor-Papadimitriou <i>et al.</i>	April 24, 2001	530	395

**U.S. PATENT APPLICATIONS**

Examiner's Initials	Serial No.	Applicant	Filing Date		

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No

**OTHER DOCUMENTS  
(Including Author, Title, Date, Pertinent Pages, Etc.)**

KAC	Zhang <i>et al.</i> , "Immune Sera and Monoclonal Antibodies Define Two Configurations for the Sialyl Tn Tumor Antigen", <i>Cancer Res.</i> 1995, 55, 3364-3368.
KAC	Toyokuni <i>et al.</i> , "Synthetic Carbohydrate Vaccines: Synthesis and Immunogenicity of Tn Antigen Conjugates", <i>Bioorg. Med. Chem.</i> 1994, 2, 1119-1132

EXAMINER

*Mark G. Genulla*

DATE CONSIDERED

10/3/05

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449

U.S. Department of Commerce  
Patent and Trademark OfficeAttorney Docket  
2003080-0054  
(SK-893-US)In re Application  
No.  
09/641,742**INFORMATION  
DISCLOSURE STATEMENT**  
(Use several sheets if necessary)Applicant: Danishefsky *et al.*Filing Date:  
August 18, 2000Group:  
1642**U.S. PATENT DOCUMENTS**

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Sub class

**U.S. PATENT APPLICATIONS**

Examiner's Initials:	Serial Number:	Applicant:	Filing Date:	Group:	Art Unit:

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Document No.	Country	International Publication Date	Translation	
				Yes	No
KAC	WO 97/03995	WIPO	February 6, 1997		
KAC	WO 98/46246	WIPO	October 22, 1998		

**OTHER DOCUMENTS**

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
KAC	Broddefalk <i>et al.</i> , "Preparation of a Glycopeptide Analogue of Type II Collagen – Use of Acid Labile Protective Groups for Carbohydrate Moieties in Solid Phase Synthesis of O-Linked Glycopeptides," <i>Tetrahedron Letters</i> , 37(17), 3011-3014, 1996.
	Chen <i>et al.</i> , "Exploration of Modalities in Building a $\alpha$ -O-Linked Systems Through Glycal Assembly: A Total Synthesis of the Mucin-Related F1 $\alpha$ Antigen" <i>J. Am. Chem. Soc.</i> , 120, 7760-7769, 1998.
	Kudryashov <i>et al.</i> "Immunogenicity of Synthetic Conjugates of Lewis <sup>x</sup> Oligosaccharide with Proteins in Mice: Towards the Design of Anticancer Vaccines," <i>Cancer Immunol Immunother</i> , 45, 281-286, 1998.

Form PTO-1449  
(REV. 8-03)

U.S. Department of Commerce  
Patent and Trademark Office

Attorney Docket  
2003080-0054  
(SK-893-US)

In re Application  
No.  
09/641,742

**INFORMATION  
DISCLOSURE STATEMENT**  
(Use several sheets if necessary)

Applicant: Danishefsky *et al.*

Filing Date:  
August 18, 2000

Group:  
1642

KAC Kuduk *et al.*, "Synthetic and Immunological Studies on Clustered Modes of Mucin-Related Tn and TF O-Linked Antigens: The Preparation of a Glycopeptide-Based Vaccine for Clinical Trials against Prostate Cancer," *J. Am. Chem. Soc.*, 120, 12474-12485, 1998.

Liu *et al.*, "Structurally Defined Synthetic Cancer Vaccines: Analysis of Structure, Glycosylation and Recognition of cancer Associated Mucin, MUC-1 Derived Peptides," *Glycoconjugate Journal*, 12, 607-617.

Paulsen *et al.*, "Synthesis of the Glycosyl Amino Acids.....," *Carbohydrate Research*, 268, 17-34, 1995

Qiu *et al.*, "Mucin Type Glycopeptides: Synthesis of Core 2, Core 6 and F1- $\alpha$  Building Blocks and Unexpected Reactions," *Tetrahedron Letters*, 38(1), 45-48, 1997.

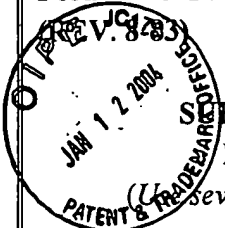
Sames *et al.*, "Convergent Total Synthesis of a Tumor-Associated Mucin Motif," *Nature*, 389, 587-591, 1997.

Toyokuni *et al.*, "Synthetic Vaccines: Synthesis of a Dimeric Tn Antigen-Lipopeptide Conjugate that Elicits Immune Responses Against Tn-Expressing Glycoproteins," *J. Am. Chem. Soc.*, 116, 395-396, 1994.

Zhang, *et al.*, "Selection of Tumor Agents as Targets for Immune Attack Using Immunohistochemistry: II. Blood Group Related Antigens," *Int. J. Cancer*, 73, 50-56, 1997.

EXAMINER:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 2003080-0054 (SK-893-US)		In re Application No. 09/641,742	
<div style="display: flex; justify-content: space-between;"> <div style="text-align: left;">  <p><b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)</p> </div> <div style="text-align: right;"> <p>Applicant: Danishefsky, <i>et al.</i></p> <p>Filing Date: August 18, 2000</p> </div> </div>				Group: 1642		<div style="display: flex; justify-content: space-between;"> <div style="text-align: right;"> <p>RECEIVED JAN 15 2004</p> </div> <div style="text-align: left;"> <p>TECH CENTER</p> </div> </div>	
<b>U.S. PATENT DOCUMENTS</b>							
Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass		
KAC	6,090,789	Danishefsky <i>et al.</i>	July 18, 2000	514	25		
KAC	US RE38,046 E	Longenecker <i>et al.</i>	March 25, 2003	424	279.1		
<b>U.S. PATENT PUBLICATIONS</b>							
Examiner's Initials:	Publication Number:	Applicant:	Publication Date:	Class	Subclass		
KAC	US 2002/0006900	Danishefsky <i>et al.</i>	January 17, 2002	514	8		
KAC	US 2002/0038017	Danishefsky <i>et al.</i>	March 28, 2002	536	53		
<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner's Initials	Document No.	Country	International Publication Date	Translation			
				Yes	No		
KAC	WO 99/15201	PCT	April 1, 1999				
	WO 01/14395 A2	PCT	March 1, 2001				
✓	WO 01/14395 A3	PCT	March 1, 2001				
<b>OTHER DOCUMENTS</b>							
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)						
KAC	Allen <i>et al.</i> , "Pursuit of optimal carbohydrate-based anticancer vaccines: preparation of a multiantigenic unimolecular glycopeptide containing the Tn, MBr1, and Lewis <sup>x</sup> antigens", <i>J. Am. Chem. Soc.</i> , 123:1890-1897, 2001.						
	Allen <i>et al.</i> , "A second generation synthesis of the MBr1 (Globo-H) breast tumor antigen: new application of the n-pentenyl glycoside method for achieving complex carbohydrate protein linkages", <i>Chem. Eur. J.</i> , 6(8):1366-1375, 2000.						
	Biswas <i>et al.</i> , "Construction of carbohydrate-based antitumor vaccines: synthesis of glycosyl amino acids by olefin cross-metathesis", <i>Tetrahedron Letters</i> , 43:6107-6110, 2002.						
	Blackwell <i>et al.</i> , "New approaches to olefin cross-metathesis", <i>J. Am. Chem. Soc.</i> , 122:58-71, 2000.						
✓	Bosse <i>et al.</i> , "Linear synthesis of the tumor-associated carbohydrate antigens Globo-H, SSEA-3, and Gb3", <i>J. Org. Chem.</i> , 67:6659-6670, 2002.						



Form PTO-1449 (REV. 8-83)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 2003080-0054 (SK-893-US)	In re Application No. 09/641,742
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)				Applicant: Danishefsky, <i>et al.</i>	
				Filing Date: August 18, 2000	
KAC		Keding <i>et al.</i> , "Hydroxynorleucine as a glycosyl acceptor is an efficient means for introducing amino acid functionality into complex carbohydrates", <i>Tetrahedron Letters</i> , 44:3413-3416, 2003.			
		Kim <i>et al.</i> , "Effect of immunological adjuvant combinations on the antibody and T-cell response to vaccination with MUC1-KLH and GD3-KLH conjugates", <i>Vaccine</i> , 19:530-537, 2001.			
		Kudryashov <i>et al.</i> , "Toward optimized carbohydrate-based anticancer vaccines: Epitope clustering, carrier structure, and adjuvant all influence antibody responses to lewis <sup>y</sup> conjugates in mice", <i>Proc. Natl. Acad. Sci. USA</i> , 98:3264-3269, 2001.			
		Nicolaou <i>et al.</i> , "A practical and enantioselective synthesis of glycosphingolipids and related compounds. Total synthesis of Globotriasylceramide (Gb <sub>3</sub> )", <i>J. Am. Chem. Soc.</i> , 110:7910-7912, 1988.			
		Ragupathi <i>et al.</i> , "A Fully synthetic Globo H carbohydrate vaccine induces a focused humoral response in prostate cancer patients: a proof of principle", <i>Angew. Chem. Int. Ed.</i> , 38(4):563-566, 1999.			
		Ragupathi <i>et al.</i> , "On the power of chemical synthesis: Immunological evaluation of models for multiantigenic carbohydrate-based cancer vaccines", <i>Proc. Natl. Acad. Sci. USA</i> , 99(21):13699-13704, 2002.			
		Slovin <i>et al.</i> , "Carbohydrate vaccines in cancer: Immunogenicity of a fully Globo H hexasaccharide conjugate in man", <i>Proc. Natl. Acad. Sci. USA</i> , 96:5710-5715, 1999.			
		Williams <i>et al.</i> , "In pursuit of an anticancer vaccine: a monomolecular construct containing multiple carbohydrate antigens", <i>Tetrahedron Letters</i> , 41:9505-9508, 2000.			
		Database BIOSIS' Online! Biosciences Information Service, Philadelphia, PA, US; 22 March 2002, Kovbasnjuk Olga <i>et al.</i> , "Glycosphingolipid Gb <sub>3</sub> as biomarker for invasive colon carcinoma cells", <i>FASEB Journal</i> , 16(5):A1200, 2002, Annual Meeting of Professional Research Scientists on Experimental Biology; New Orleans, LA, USA, April 20-24, 2002.			
		International Search Report issued for PCT application PCT/US03/22657			
EXAMINER <i>[Signature]</i>		DATE CONSIDERED 10/3/05			
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					

Form PTO-1449 (REV. 8-83)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket: 2003080-0054 (SK-893-US)	In re Application No. 09/641,742
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>  <i>(Use several sheets if necessary)</i>		Applicant: Danishefsky <i>et al.</i>	
		Filing Date: August 18, 2000	Group: 1642

### U. S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
KAC	5,683,674	Taylor-Papadimitriou <i>et al.</i>	Nov. 4, 1997	424	1.49
KAC	6,222,020	Taylor-Papadimitriou <i>et al.</i>	April 24, 2001	530	395

### U.S. PATENT APPLICATIONS

Examiner's Initials	Serial No.	Applicant	Filing Date		

### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No

### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

KAC	Zhang <i>et al.</i> , "Immune Sera and Monoclonal Antibodies Define Two Configurations for the Sialyl Tn Tumor Antigen", <i>Cancer Res.</i> 1995, 55, 3364-3368.
KAC	Toyokuni <i>et al.</i> , "Synthetic Carbohydrate Vaccines: Synthesis and Immunogenicity of Tn Antigen Conjugates", <i>Bioorg. Med. Chem.</i> 1994, 2, 1119-1132

EXAMINER

*Karen J. Canella*

DATE CONSIDERED

10/3/05

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



<b>Form PTO-1449</b> <b>(REV. 8-83)</b>		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 2003080-0054 (SK-893-US)		In re Application No. 09/641,742	
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>  <i>(Use several sheets if necessary)</i>				Applicant: Danishefsky <i>et al.</i>		<div style="writing-mode: vertical-rl; transform: rotate(180deg);"> <b>RECEIVED</b>            JUL 08 2002            TECH CENTER 1600/2900         </div>	
				Filing Date: August 18, 2000			
<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner's Initials	Document No.	Country	Date	Translation			
				Yes	No		
KAC	EP 341252	EP	11/19/97	}	}		
KAC	WO 01/14395	PCT	03/01/01	}	}		
Examiner's Initials	<b>OTHER DOCUMENTS</b> (Including Author, Title, Date, Pertinent Pages, Etc.)						
KAC	Bilodeau M.T., "Total Synthesis of a Human Breast Tumor Associated Antigen", <i>J. Am. Chem. Soc.</i> , 117:7840-7841, 1995.						
	Boehm T. <i>et al.</i> , "Development of a Novel Silyl Ether Linker for Solid-Phase Organic Synthesis" <i>J. Org. Chem.</i> , 61:6498-6499, 1996.						
	Danishefsky <i>et al.</i> "From the Laboratory to the Clinic: A Retrospective on Fully Synthetic Carbohydrate-Based Anticancer Vaccines" <i>Angew. Chem. Int. Ed. Engl.</i> , 39:836-863, 2000.						
	Lay L. <i>et al.</i> , "Oligosaccharides Related to Tumor-Associated Antigens", <i>Helv. Chim. Acta</i> , 77:509-514, 1994.						
	Randolph J.T. <i>et al.</i> , "An Interactive Strategy for the Assembly of Complex, Branched Oligosaccharide Domains on a Solid Support: A Concise Synthesis of the Lewis <sup>b</sup> Domain in Bioconjugatable Form", <i>Angew. Chem. Int. Ed/ Engl.</i> , 33(14):1470-1473, 1994.						
✓	* Yura <i>et al.</i> , "Preparation of oligosaccharide-linked polystyrene and method for immobilization of lectin and base materials for cells", abstract, Jpn. Kokai Tokkyo Koho (Japan), 03 December 1996.						
EXAMINER <i>Norm D. Canella</i>				DATE CONSIDERED <i>10/3/05</i>			
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

\* Cited document is not at present available to the undersigned, or is available in the file of a prior related application relied upon for an earlier filing date under 35 U.S.C. § 120.